### **REMARKS**

By the Response, claims 27 and 28 have been amended to particularly point out and distinctly claim the subject matter of the invention. Support for the amendments can be found in the specification, e.g., at page 16, lines 12-15 and Figure 3. No new matter has been added. Accordingly, pending claims 1-28 are respectfully submitted for consideration. Approval and entry of the amendments are respectfully requested.

### Rejection Under 35 U.S.C. §102(b)

Claims 1-2, 6-10, 12-19, 21-22, and 24-28 are rejected under 35 U.S.C. §102(b) as being anticipated by List (U.S. Patent Application Publication No. 2003/0028126). Applicant respectfully traverses the rejection at least for the reason that List fails to describe each and every limitation recited in the rejected claims.

As previously pointed out, List discloses a first member 20, a second member 4, and a pair of link arm 12, 13 that connect these members (see Figures 1a-1d). However, a direction change of the second member 4 from the lancing direction to the retreating direction occurs only while the first member 20 assumes its lower limit position (in the order of Figures 1c→1d→1a), namely while the first member does not move. See paragraphs [0034-0037] of List. Therefore, List does not meet the claimed limitation of claim 1 that requires "a directional change of movement of the second member from the lancing direction to the retreating direction is performed during a one-way stroke of the first member in one of the lancing direction and the retreating direction" (emphasis added). Further, in List, the second member 4 keeps stationary while the first member 20 reciprocates, whereas the first member 20 keeps stationary while the second member 4 reciprocates. Therefore, List also fails to teach or suggest the limitations set forth in the last two paragraphs of claim 1.

Applicant respectfully wishes to bring the Examiner's attention to the spring 29 of List, where it is provided only to keep the links 13, 14 in the bent state, as shown in Figure 1a or 1c. The lancing force  $F_A$  is applied by a leaf spring 31 causes the lancet 4 to advance and retreat only while the first member 20 is kept at the advanced position by the urging force of the coil spring 29, as clearly shown in Figures  $1c \rightarrow 1d \rightarrow 1a$ .

Moreover, the Examiner may have improperly adopted the "capable of" type interpretation of List. Though this manner of interpretation may be acceptable with respect to the claimed limitation that sets forth only the capability, such interpretation should not apply with respect to the claimed "movement conversion means" that provides the function which is actually performed. As pointed out above, List does not meet the claimed limitation "a directional change of movement of the second member from the lancing direction to the retreating direction is performed during a one-way stroke of the first member in one of the lancing direction and the retreating direction".

In view of the above remarks, Applicant respectfully submits that independent claim 1, as well as the claims that depend therefrom, is patentable over List.

With respect to independent claim 27, this claim has been amended to set forth among other things that the pin about which the first link arm and the second link arm pivot is a stationary pin held at a fixed position relative to the housing. The underlined new limitation is supported by the description at lines 12-15, page 16 of the specification, taken with Figure 3 wherein the pin 30c is shown to be fixed to the housing 2. In addition, independent claim 27 also recites "an angle between the first and second link arms in a pivoting direction of the first and second link arms about the stationary pin is <u>invariable</u> regardless of positions of the first and second members."

In rejecting independent claim 27, the Examiner interprets the pin 16 of List as a fixed pin, which is distinct from that of the pin as set forth in independent claim 27. However, the position of the pin 16 of List changes relative to the housing 22, as clearly shown in Figures 1(a) to 1(d). Further, the term angle between the two link arms 13, 14 also changes in response to the movement of the elements 4, 21. Therefore, the pin 16 of List is not equivalent to the pin as recited in independent claim 27 that is a stationary pin being held at a fixed position relative to the housing.

Independent claim 28, as amended, also recites the same features as amended claim 27.

For similar reasons mentioned above, Applicant respectfully submits that both independent claims 27 and 28 are patentable over List. Reconsideration and withdrawal of the rejection of these claims are respectfully requested.

Claims 1-4, 6-11, 14-18, 20 and 24 are rejected under 35 U.S.C. §102(e), as being anticipated by Garthe et al. (U.S. Patent Application Publication No. 2003/0225429). Applicant respectfully traverses the rejection at least for the reason that Garthe et al. fail to describe each and every limitation recited in the rejected claims.

As pointed out previously, Garthe et al. disclose, in Figures 4A-4C, a blood withdrawal system which includes a mass 60, a rotatable guide sleeve 51 having cam grooves 52, 53, and a lancet holder 40. When the guide sleeve 51 rotates, the mass 60 and the lancet holder 40 reciprocate in accordance with the profiles of the respective cam grooves 52, 53. Hence, the reciprocal movement of the mass 60 is not converted into the reciprocal movement of the lancet holder 40 because the lancet holder 40 can reciprocate even if the mass 60 is eliminated. Accordingly, Garthe et al., likewise, also fail to teach or suggest the claimed "movement convertion means," as set forth in independent claim 1.

In view of the foregoing remarks, independent claim 1, as well as the claims that depend therefrom (claims 2-4, 6-11, 14-18, 20 and 24), is also patentable over Garthe et al. Applicant respectfully requests the reconsideration and withdrawal of the §102(e) rejection in view of Garthe et al.

### Rejection Under 35 U.S.C. §103(a)

Claim 5 is rejected under 35 U.S.C. §103(a), as being unpatentable over Garthe et al. (U.S. Patent Application Publication No. 2003/0225429). Applicant respectfully traverses the rejection. Claim 5 depends from claim 1 and is patentable over Garthe et al. for at least the same reasons discussed regarding independent claim 1. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claim 5.

Claim 23 is also rejected under 35 U.S.C. §103(a), as being unpatentable over List (U.S. Patent Application Publication No. 2003/0028126). Applicant respectfully traverses the rejection. Like claim 5, Applicant respectfully submits that claim 23, which depends on claim 1, is also patentable over List for at least the same reasons discussed regarding claim 1. Accordingly, reconsideration and withdrawal of the rejection of claim 23 are respectfully requested.

## <u>Usage of Means-Plus-Function Language in Independent Claim 1</u>

With respect to independent claim 1, the Examiner asserted that the usage of the "movement conversion means for" language in the claim has failed the three prong test set forth in MPEP 2181 for determining eligibility of claim language to invoke 35 U.S.C. §112, 6<sup>th</sup> paragraph. According to the Examiner, the failure of using the "means for" language is because "Applicant has claimed structure, material, or acts for achieving the specified function." See Office Action of March 1, 2011, at pages 13-15. Applicant respectfully disagrees with the Examiner and believes that his rejection is improper for the following reasons discussed hereinbelow:

The three prong test includes the following three requirements:

- (a) the claim limitations must use the phrase "means for" or "step for;"
- (b) the "means for" or "step for" must be modified by functional language; and
- (c) the phrase "means for" or "step for" must not be modified by <u>sufficient</u> structure, material or acts for achieving the specified function. (Emphasis added)

Applicant respectfully submits that the claimed "movement conversion means," as recited in independent claim 1, is not exactly the same as the "lancet moving mechanism" that includes the movable plate 31 and the lancet holder 32, in addition to the link member 30. Rather, the claimed "movement conversion means" corresponds to the link member 30 of the first embodiment of the invention.

Moreover, and even more importantly, item (c) of the three prong test requires that the "means for" limitation include a <u>sufficient</u> structure to disqualify for provoking the 35 U.S.C. §112, 6<sup>th</sup> paragraph. Even if the "first member" and the "second member" are considered to be structural parts of the claimed "movement conversion means" as pointed out by the Examiner, these structural parts themselves are not at all sufficient for realizing the recited function of the "movement conversion means." This was why Applicant has to rely on the means-plus-function language under 35 U.S.C. §112, 6<sup>th</sup> paragraph, particularly in view of the fact that it is difficult to structurally define the present invention in a generic claim that would cover all of the various embodiments of the present invention.

In view of the above remarks, Applicant respectfully submits that the Examiner's reasoning for not allowing Applicant to use the "means for" language in

independent claim 1 is improper. Applicant respectfully requests the Examiner to reconsider his decision on such usage.

In sum, List, as well as Garthe et al, fails to teach or suggest the claimed movement conversion mechanism which includes a stationary pin held at a fixed position relative to a housing, and a link member supported on the stationary pin for pivoting about the stationary pin, wherein the link member includes a first arm carrying a first movable pin connected to the first member, and a second arm carrying a second movable pin connected to the second member, wherein the first arm is connected to the second arm at an angle that is defined as an angle between the first and second arms in a pivoting direction of the link member about the stationary pin, and wherein the angle is invariable regardless of positions of the first and second members. Accordingly, both List and Garthe et al. fail to anticipate and render obvious the lance apparatus as set forth in independent claims 1, 27 and 28, as well as the claims that depend therefrom.

Applicant would like to mention that the corresponding Japanese application has now been issued as JP Patent No. 4621853, with two independent claims, one of which corresponds to pending claim 1 of the present application.

# **CONCLUSION**

In view of the amendments to the claims, and in further view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is requested that pending claims 1-28 be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the Applicant's representative, the Examiner is invited to contact the undersigned at the numbers shown.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

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